reagents used to measure by immunochemical techniques the inter-*alpha* trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-*alpha* trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 53 FR 11253, Apr. 6, 1988; 65 FR 2313, Jan. 14, 2000]

Subpart G—Tumor Associated Antigen immunological Test Systems

§866.6010 Tumor-associated antigen immunological test system.

(a) *Identification*. A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) *Classification*. Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s) to FDA,'' and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.

[62 FR 66005, Dec. 17, 1997]

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

Subpart B—Diagnostic Devices

Subpart C—Monitoring Devices